

**Notice of Allowability**

Application No.

09/518,297

Applicant(s)

LIM ET AL.

Examiner

Art Unit

Chih-Min Kam

1653

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/12/05.
2. ☒ The allowed claim(s) is/are 52,53 and 60-63.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☒ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☒ to Paper No./Mail Date 10/9/01.
    - (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date 20050614.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☒ Other correction of inventorship.

Art Unit: 1653

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

**Examiner's Amendments to the Specification:**

-Replace the paragraph at page 1, lines 6-7 with the following paragraph:

This application claims priority to U.S. Provisional application Serial Nos. 60/154,605, filed September 17, 1999, and 60/122,513, filed March 3, 1999, expressly incorporated by reference herein.

-Replace the paragraph beginning on page 7, line 42 with the following:

Figure 4B depicts the effect of various concentrations of 21x on reporter expression in *E. coli* strains that carry *rrnB* P1 promoter constructs (the sequences for which are presented in Fig. 4A), fused to a *lacZ* reporter on the chromosome as a phage mono-lysogen, as indicated in the figure. Cells were incubated with or without 21x for 24 hrs and promoter activities assayed following treatment. Promoter activities are expressed as a percentage of basal promoter activity. All samples were in triplicate, the error bars represent standard errors of the mean (SEM) for three separate experiments.

-Replace the paragraph beginning on page 8, line 11 with the following:

Figure 6 depicts the results of DNA binding studies with the modified UL9 DNA response sequences presented in Fig. 5 and <sup>32</sup>P labeled oligos, incubated with various concentrations of 21x. The modified sequences include "YK 202LX" (shown as diamonds, SEQ ID NO:18), "YK 202RX-A" (shown as squares, SEQ ID NO:19), and "YK 202RX" (shown as triangles, SEQ ID NO: 21).

Art Unit: 1653

-Replace the amino acid sequence for SEQ ID NO:8 in the Sequence Listing Table at page 4 of the amendment filed May 12, 2005 with the following amino acid sequence:

APPTDVSLGDELHLDGEDVMALDDFDLDMLGDGDSPPGPGFTPHDSAPYGALDY  
FEFEQMFTDALGIDEYG.

-Replace the amino acid sequence for SEQ ID NO:9 in the Sequence Listing Table at page 4 of the amendment filed May 12, 2005 with the following amino acid sequence:

DALDDFDLDML DALDDFDLDML DALDDFDLDML DALDDFDLDML.

The following is an **Examiner's Statement of Reasons for Allowance**: The following references appear to be the closest art to the claimed invention. Goldstein *et al.* (U. S. Patent 5,527,690) teach sterol regulatory element (SRE) binding proteins (SREBP) are involved in the regulation of genes in cholesterol metabolism that is under the control of SRE-1, where SREBP-1, which acts not only as a transcriptional regulatory protein, but also as a DNA binding compound, binds to SRE-1 DNA sequences to promote transcription and gene expression; and Bujard *et al.* (WO 94/29442) teach a system for regulating expression of eukaryotic genes using components of the Tet repressor/operator/inducer system of prokaryotes in a host cell, and transcription of a nucleotide sequence operably linked to at least one tet operator sequence is stimulated by a tetracycline (Tc)-controllable transcriptional activator fusion protein (tTA), where the tTA acts not only as a transcriptional regulatory protein, but also as a DNA binding compound. However, the references do not teach or suggest a molecular switch comprising a DNA response element for a transcriptional regulatory protein, operably linked to a first promoter, a non-native compound binding sequence for binding to a DNA binding compound, a transgene under the control of said first promoter, and a DNA binding compound, wherein the DNA binding compound, when bound to the binding sequence, is effective to modulate binding of the transcriptional regulatory protein to the DNA response element. Therefore, the claims are allowable over the art of record.

### ***Objection to Drawings***

Figs. 2A and 2B are objected to because the nucleotides in the sequence are not properly spaced. Please submit a whole set of formal drawings.

Art Unit: 1653

***Correction of Inventorship***

In view of the papers filed August 3, 2000, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(c). The inventorship of this application has been changed by addition of Albert W. Tam.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

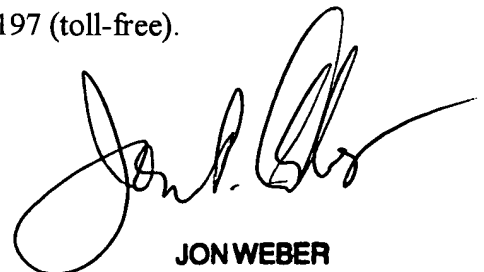
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner

CMK

CMK

June 14, 2005

  
**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**